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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/344,526	06/24/1999	MARK S. CHEE	A-66828-2/DJ	9163

7590

06/17/2002

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/17/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/344,526

Applicant(s)

Chee et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14, 16-28, and 30-35 is/are pending in the application.
- ~~4a) Of the above, Claim(s) 1-7, 15, and 29 have been canceled.~~ ~~4b) Claim(s) 1-7, 15, and 29 have been withdrawn from consideration.~~
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14, 16-28, and 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 2 sheets
- 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The request, filed 4/1/02, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/344,526 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' arguments, filed 4/1/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 8-14, 16-28, and 30-35 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant specification on pages 5-6, for example, the instant invention utilizes coding and decoding via distinct signature ligands etc. Such distinct coding/decoding ligands are apparently distinct via being different regarding the coded and decoded signatures therein. It is noted that claim 8, for example, cites the presence of first and second subpopulations without requiring that their respective bioactive agents be either distinct or different in any way when comparing said first and second agents. It might be assumed that the separate

citation of such first and second agents are distinct or different from each other but such an assumption is deemed to lack a clear and concise limitation regarding these agents. Thus, the claim is vague and indefinite as not citing concisely any distinction between agents in various populations and/or subpopulations. Thus, a possible interpretation is that the agents in claim 8 may be all identical. Clarification via clearer claim wording to make the claims commensurate in scope with the specification is requested. This unclarity is also present in remaining instant claims either directly or indirectly due to claim dependence wherein agents lack a limitation as to their being either identical or distinct. Lastly, it is noted that the decoder ligands as cited in the claims also lacks clarity as to being either identical or distinct. It is noted that the "specific" binding of decoding ligands has been amended into the claims, such as claim 9, but without any limitation as to what this specificity is directed to. Is it to distinguish between bioactive agents? Is it "specific" over analytes? Is it "specific" to the microspheres? It is noted that claim 10 indicates specificity to bioactive agents but is not clear as to whether this specificity distinguishes different bioactive agents or whether it is specific in being able to distinguish bioactive agents generically versus non-bioactive agents, for example.

Claims 27 and 28, line 1 of each claim, cite "said

identifier binding ligands" which lacks antecedent basis in claims 8 or 14 from which claims 27 and 28 depend.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 8-14, 21, 23-28, 30-33, and 35 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Brenner (P/N 5,863,722).

Brenner discloses the preparation of microparticles or beads with polynucleotides, that is, nucleic acids, attached thereto in column 3, lines 1-23. Solid phase supports that are usable therewith are summarized in column 9, line 9, through column 10, line 43, as inclusive of various solid supports such as beads, slides, plates, arrays, etc. It is noted that microspheres are also characterized as being beads in the instant specification on page 5, lines 19-22. In column 19, line 17, through column 21,

line 13, the practice of microparticles with polynucleotides or nucleic acids thereon is described wherein enzymatic processes or binding events are observed. It is noted that preferably the labeled microparticles are randomly disposed on a plane as noted in column 20, lines 42-46. Additionally, Brenner discloses the utilization of identifier binding ligands, such as biotin (which is also detectable as a label, if desired), with avidin attachment/decoding entities on the solid support in column 20-21, bridging paragraph, which anticipates the instant decoding identifier ligand limitations. These decoders in the instant claims lack any distinctness limitations as noted also in the above rejection under 35 U.S.C. § 112, second paragraph. It is also noted that these avidin binding sites are discrete and detectable as labels, if desired, for each avidin molecule as also required in claims 8 etc. Also, regarding instant claims 8 etc. Brenner discloses the utilization of bioactive agents for decoding ligands to complementary tags in column 19, lines 20-22.

Claims 8-14, 16, 17, 21, 23-25, 30, 31, 33, and 35 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Chelsky et al. (P/N 5,856,083).

Chelsky et al. disclose a lawn assay wherein solid supports such as beads are randomly immobilized on a lawn at discrete sites, which can be determined if desired after immobilization, such as the bottom of a petrie plate followed by the application

of test enzyme etc. as summarized in column 2, lines 10-37, and column 7, lines 12-35, which test enzyme decodes the beads regarding the presence or absence of enzyme activity therewith. Various target analytes are summarized in column 3, lines 20-67, including protein, DNA, and RNA (nucleic acids) as also instantly claimed. The library of solid supports, preferably beads (interpreted as microspheres as noted in the above rejection), is thus screened as described in the bridging paragraph between columns 2 and 3. These beads are not labeled but rather are assayed in the method via subsequent methods involving visualization of some type. The random distribution of beads over a patterned surface is disclosed in Chelsky et al. in column 7, lines 20-35, including the decoding of the image of activity on the array of beads as well as the washing of the bead solution over the a thin glass disk which requires washing energy input in order to move the solution for said washing. These disclosures anticipate the above listed instant claims.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or

provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-14, 16-28, and 30-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, 16-22, and 24 of copending application Serial No. 09/748,706. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain common embodiments directed to random microsphere distribution practice. In order to obtain a definition of what is meant by the distribution of microspheres on the substrate surface in the claims of 09/748,706 one must utilize the specification as a Dictionary to define what is meant by distribution. It is noted that a patterned surface is generally utilized with a random distribution of microspheres over the surface as defined in the specification of 09/748,706 at page 6, lines 22-34. Thus, the embodiments of the instant claims drawn to random microsphere distribution over the substrate sites is also embodiments of the claims of 09/748,706 thus supporting this provisional double patenting rejection.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 14, 2002

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER